REMARKS

In the Office Action dated June 4, 2007, claims 1-4, 6-10 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Scarborough in view of Krause et al. This rejection is respectfully traversed for the reasons discussed below.

Applicants note with appreciation that claims 5 and 11 were stated to be allowable if rewritten in independent form, however, in view of the traversal of the aforementioned rejection, these claims have been retained in dependent form at this time.

In substantiating the rejection based on Scarborough and Krause et al, the Examiner stated the Scarborough reference discloses the placement of a plurality of x-ray detectable markers on an anatomically implanted medical implant, as well as disclosing a method for viewing the implant after surgery is performed by means of x-ray imaging, in order to assess the procedure.

The Examiner acknowledged that the Scarborough reference does not disclose a system for assessing the position change of the implant, and thereby determining if a positional change has occurred. The Examiner relied on the Krause reference as disclosing the use of post-surgical x-ray images from at least two perpendicular directions, together with reference point data and edge detection, to verify the location and effectiveness of a surgically implanted Fixator frame. The Examiner acknowledged that the Krause et al reference does not discuss probability factors, but instead makes use of coordinate data to verify if the implant is in the correct position. The Examiner stated that "through the memory means provided in Krause et al, and repeating the same location process later (column 9, lines 20-45),

the operator could easily compare the coordinate values to determine if a positional change has occurred (column 20, lines 1-65)."

The Examiner stated it would have been obvious to a person of ordinary skill in the art to have incorporated the coordinate system, memory means, and position acquisition and comparison means of Krause et al "along side" the medical implant containing x-ray detectable markers of Scarborough, for the purpose of verifying implant position, "in the way which Scarborough teach towards."

Applicants agree that the Scarborough reference discloses incorporating radiopaque markers into an implant in order to be able to recognize these markers in one or more post-surgery x-ray images. The markers disclosed in the Scarborough reference are exclusively located on or in the implant itself. There is no disclosure in the Scarborough reference of providing other markers, that are visible in x-ray images, in the environment of the implant, as set forth in the independent claims of the present application.

Applicants do not agree completely with the Examiner's characterization of the teachings of the Krause et al reference. The Krause et al reference discloses planning software for pre-operative planning and execution of a surgical procedure, namely the implantation of a fixator frame for a bone. For this purpose, a three-dimensional solid bone model is generated from several two-dimensional x-ray images, which are obtained from the patient prior to the implantation.

For the purpose of generating this model, a 3D construction of the bone geometry must be performed in the operation of the Krause et al software. The geometrical, three-dimensional form of the fixator frame is provided by a fixator data base. The selection and positioning of the fixator frame thus can be simulated as a

feature of pre-operative planning. For generating the 3D model of the bone, at least two 2D x-ray images must be obtained from different angles at substantially the same time, i.e., without any movement of the patient occurring between those images. In fact, it must be assumed that no movement whatsoever of the bone occurs between the respective times that these 2D x-ray images are obtained, otherwise they would be useless for generating the 3D model fo the bone. Therefore, even if these 2D images from different projection directions are not taken precisely simultaneously, it is essential to the intended operation of the Krause et al reference, that, if a single imaging arrangement is used to obtain both x-ray images, this imaging arrangement must be moved from one projection direction to the other sufficiently quickly such that no bone movement occurs in between the times that the respective x-ray images are obtained from the different projection directions.

After implantation of the fixator frame at a later point in time, additional 2D x-ray images are obtained from different angles (projection directions), in order to be able to detect or identify any deviation of the position of the implanted fixator frame from the planned position and orientation. For assisting in the identification of the fixator frame in these x-ray images, the fixator frame has identifiable and detachable visual targets attached thereto.

In order to be able to identify any deviation of the actual implanted position from the intended position, a three-dimensional reconstruction of the fixator frame must be undertaken, which is based on the post-surgery x-ray images, for comparison with the 3D model generated in the pre-operative planning.

Therefore, the following basic differences exist between the subject matter claimed in the independent claims of the present application and the disclosure of Krause et al.

The Krause et al reference does not teach disposing x-ray detectable markers in an anatomical environment of the implant. In the Krause et al reference, the fixator frame is the implant and, just as in the Scarborough reference, the x-ray detectable markers are placed only on the implant itself, not in the environment of the implant.

The independent claims of the application as originally filed referred to the x-ray-detectable items in the environment as being "x-ray detectable markers" and referred to the x-ray-detectable items on the implant as being "x-ray detectable points," and therefore Applicants submit it was clear from the language of the claims as originally filed that the markers in the anatomical environment are different from the x-ray detectable points on the implant. Nevertheless, the language of the independent claims has been editorially amended to make this even more apparent.

Additionally, in the Krause et al reference, 3D models of the bone and of the implant (fixator frame) are generated, and must be generated, in order to detect any deviation between the planned position and the actual position. In the subject matter disclosed and claimed in the present application, no such 3D reconstruction of any type (a model or otherwise) is necessary, and in fact it is one of the basic objects of the method and apparatus disclosed and claimed in the present application to avoid such 3D reconstruction, as explicitly stated in the language of each of the independent claims. The method and apparatus disclosed and claimed in the present application can operate with only two 2D images being obtained whereas, at

a minimum, the Krause et al reference must obtain four 2D images (two 2D images respectively from two different projection angles during planning, and two 2D images respectively from different projection angles after the implantation).

Moreover, the Krause et al reference does not disclose determination of a first or second *distribution* of the markers in first and second two-dimensional x-ray images, as also explicitly set forth in the claims. Additionally, as acknowledged by the Examiner, the Krause et al reference does not disclose calculation of a degree of probability from the aforementioned distribution and making a determination, from that calculated degree of probability, as to whether movement of the implant has occurred.

The method and apparatus disclosed and claimed in the present application provide a very simple and uncomplicated procedure, with a minimum number of x-ray exposures being acquired, and with no 3D reconstruction being necessary, in order to identify movement of an implant with respect to its anatomical environment.

The Examiner's statements in the sentence bridging pages 2 and 3 of the Office Action regarding what a person of ordinary skill "could" do are no more than speculation, or an "obvious to try" proposal. More importantly, however, even if the procedure disclosed in Krause et al were repeated for comparison purposes, as proposed by the Examiner, this would still not only involve, but require, not one but two 3D reconstructions, as expressly precluded in the subject matter of the independent claims of the present application.

Therefore, Applicants submit that none of claims 1-4, 6-10 or 12 would have been obvious to a person of ordinary skill in the field of medical imaging, based on

the teachings of Scarborough and Krause et al, under the provisions of 35 U.S.C. §103(a).

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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